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08/793,833	02/18/97	SCHUMACHER J 69430	

WELSH & KATZ LTD
120 SOUTH RIVERSIDE PLAZA
22ND FLOOR
CHICAGO IL 60606-3913

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EXAMINER	
BEISNER, W	
ART UNIT	PAPER NUMBER
1744	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/793,833

Applicant(s)

SCHUMACHER ET AL.

Examiner

William H. Beisner

Group Art Unit

1744



☒ Responsive to communication(s) filed on Feb. 20, 1998 and May 15, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9, 12, 13, 15-19, and 21-69 is/are pending in the application.

Of the above, claim(s) 1-6, 23-28, 32, and 60-69 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 7-9, 12, 13, 15-19, 21, 22, 29-31, and 33-59 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Claims 1-6 and 23-28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 5.

2. Newly submitted claims 32 and 60-69 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions of new claims 32 and 60-69 and the originally filed examined claims are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The inventions covered by these two groups of claims are two different devices which are not disclosed as being capable of use together. Additionally, as recited in the specification the two separate devices have different modes of operation and different functions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the

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merits. Accordingly, claims 32 and 60-69 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

3. Claims 13 and 16 are objected to because of the following informalities:

Claims 13 and 16 depend from canceled claims 11 and 10, respectively.

Appropriate correction is required.

Note, these claims will be examined as though they depend from claim 7.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7-9, 17-19, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Amended claim 7 includes the new limitation that the device is for the measurement of the concentration and activity of enzymes. The originally filed disclosure is silent as to the use of the device for measuring the concentration as well as the activity of an enzyme in a sample.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7-9, 12, 13, 15-19, 21, 22, 29-31 and 33-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite because the metes and bounds of the claim cannot be clearly determined. It is difficult to distinguish between the preamble of the claim and the body of the claim. It appears that the transition between the preamble and the body of the claim involves the use of the language "having". If so, is the recited "vessel" intended to be part of the claimed device? The claim as amended now includes the language that the concentration and activity are measured by the device. However, the body of the claim only recites a means for detecting the activity of at least one enzyme. How or by what means is the concentration determined. Also, what is the difference between concentration and activity, especially in view of the fact that inhibitors for the enzyme are being removed from the sample? What are "such enzyme inhibitors"? What is intended by "inhibitors corresponding to at least one enzyme in the sample"?

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Is this the same enzyme in which the activity is being detected? “the end of the column” lacks antecedent basis. Which end? Finally, it is not clear if the means for detecting is detecting the activity of the enzyme recited in the preamble or some other enzyme which may also be included in the sample. Additionally, what positively recited structure in the body of the claim provide the automatic and continuous intended function of the preamble of the claim?

In claim 8, “the substance” lacks antecedent basis.

In claim 13, “said control device” lacks antecedent basis.

In claim 16, “the buffer” lacks antecedent basis.

In claim 17, “the column buffer” lacks antecedent basis. Also, it is not clear what further structure is being recited. The valve/pump assembly has already been recited. Are additional structures being recited in this claim in addition to the valve/pump assembly?

In claim 18, “the detector” lacks antecedent basis.

In claim 19, what is intended by “guarantee”? Is this the same as “maintain”?

In claim 21, it is not clear how the recited “at least one valve” structurally cooperates with the rest of the previously recited device. Where is this valve in relation to the column and sample input lines?

In claim 22, “the vessel” lacks antecedent basis. Is this the vessel in which the sample is provided? If so, it is not clear from the instant disclosure that substrate addition and detection are associated with this vessel.

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Claim 29 is indefinite for similar reasons as set forth with respect to claim 7. With respect to the recited means for enabling passage, while the claim recites that sample can pass through or around the column, it is not clear if the sample is still going through the rest of the system components even when passing around the column.

In claim 35, "the column buffer" lacks antecedent basis.

In claim 36, "the column buffer" lacks antecedent basis.

In claim 37, it is not clear what further structure is being recited. The valve/pump assembly has already been recited. Are additional structures being recited in this claim in addition to the valve/pump assembly? Also, "the test tube" lacks antecedent basis. "the valve/pump arrangement" lacks antecedent basis.

In claim 39, "the test tube" lacks antecedent basis.

In claim 40, it is not clear how the recited "at least one valve" structurally cooperates with the rest of the previously recited device. Where is this valve in relation to the column and sample input lines? "the valve/pump arrangement" lacks antecedent basis.

In claim 41, the language "to run and control and if need be" is indefinite. Does the computer run and control or not?

Claim 30 is indefinite for similar reasons as set forth with respect to claims 7 and 29. Additionally, with respect to the degree of dilution, degree of dilution of the sample with respect to what?

In claim 44, "the column buffer" lacks antecedent basis.

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In claim 45, “the column buffer” lacks antecedent basis. Also, it is not clear if the recited arrangement for measuring degree of dilution is the same or different from that recited in claim 30.

In claim 46, “the valve/pump arrangement” lacks antecedent basis. It is not clear what further structure is being recited. The valve/pump assembly has already been recited. Are additional structures being recited in this claim in addition to the valve/pump assembly? Also, “the test tube” and “the column buffer” lack antecedent basis.

In claim 48, “the test tube” lacks antecedent basis.

In claim 49, it is not clear how the recited “at least one valve” structurally cooperates with the rest of the previously recited device. Where is this valve in relation to the column and sample input lines? “the valve/pump arrangement” lacks antecedent basis.

In claim 50, the language “to run and control and if need be” is indefinite. Does the computer run and control or not?

Claim 31 is indefinite for similar reasons as set forth with respect to claims 7 and 29. Also, what is intended by the language “having binding a enzyme inhibitor”?

In claim 53, how does the recited control device differ from that recited in claim 31 and how does the claim differ from the device encompassed by claim 12? “the column buffer” lacks antecedent basis.

In claim 54, “the column buffer” lacks antecedent basis.

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In claim 55, "the valve/pump arrangement" lacks antecedent basis. Also, claim 31 recites a buffer which appears to be a measuring buffer. Are any of the buffers recited in claim 55 the same as the buffer recited in claim 31? "the column buffer" and "the test tube" lack antecedent basis.

In claim 57, "the test tube" lacks antecedent basis.

In claim 58, it is not clear how the recited "at least one valve" structurally cooperates with the rest of the previously recited device. Where is this valve in relation to the column and sample input lines? "the valve/pump arrangement" lacks antecedent basis.

In claim 59, the language "to run and control and if need be" is indefinite. Does the computer run and control or not?

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 7-9, 13, 16-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Showa Denko Kabushiki Kaisha (EP 0 329 190) in view of Koohmaraie et al.(J. Anim. Sci.).

The reference of Showa discloses a device for detecting the activity of enzymes which includes a column, 6, filled with a substance which is capable of removing enzyme inhibitors; a valve/pump arrangement, 1 and 2, in series with the column, 6; a test vessel, 4; temperature

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control structure, 3; and a detector, 5, which can be a fluorimeter (See column 7, lines 10-24).

Column, 6, is capable of being used repeatedly and/or is capable of being exchanged.

If it is determined that the column, 6, of the reference of Showa is not inherently "capable of binding such enzyme inhibitors which correspond to at least one enzyme in the sample", the reference of Koohmaraie et al. discloses that it is known in the art to measure the activity of a specific enzyme in a sample wherein the sample is first contacted with a column of Sepharose so as to remove inhibitors of the enzyme to be detected.

As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference so as to perform the method of Koohmaraie et al. for the known and expected result of providing a system recognized in the for performing the method of the reference of Koohmaraie et al. since both references are drawn to the detection of enzyme activities wherein the sample is first treated to remove an inhibitor substance

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Showa Denko Kabushiki Kaisha (EP 0 329 190) in view of Koohmaraie et al.(J. Anim. Sci.) and further in view of Stevens (US 4,762,617).

The reference of Showa in view of Koohmaraie et al. has been discussed above.

Claim 22 differs by reciting that the sample and buffer are alternatively supplied to the column and that the system is automatically controlled by a computer device.

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The reference of Stevens discloses a system for introducing a sample into a separation column wherein the buffer and sample are alternatively supplied and the system is controlled by a computer device.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to automate the operation of the systems of the primary reference by using a computer control. With respect to the sample supply, use of a sample supply system as disclosed by the reference of Stevens would have been obvious for the known and expected result of providing a means recognized in the art for automating the addition of a plurality of different samples to the detection system.

Response to Arguments

11. Applicant's arguments filed Feb. 20, 1998 and May 15, 1998 have been fully considered but they are not persuasive.

With respect to the combination of the references of Showa and Koohmaraie, Applicants argue that the combination of the reference is not proper because the process of Koohmaraie is a batch process.

In response to applicant's argument that the batch process of Koohmaraie cannot be combined with the flow through device of Showa, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the

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references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In view of the fact that the reference of Showa discloses the use of a separation column, 6, and in view of the fact that the reference of Koohmaraie discloses that enzyme activity can be measured by first removing inhibitors with a separation column, the Examiner believes that the level of skill in the art would allow one of ordinary skill in the art to recognize that the column, 6, of Showa can be modified so as to separate inhibitors as suggested by the reference of Koohmaraie. The same response holds true for Applicants' comments concerning the fact that the reference of Showa employs a substrate on a column while the reference of Koohmaraie uses a different procedure and reaction mechanism. Note, both references are using a substrate to detect the activity of the enzymes in the sample after the separation step.

Allowable Subject Matter

12. Claims 12, 15, 29-31 and 33-59 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

13. Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities

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remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **William H. Beisner** whose telephone number is **(703) 308-4006**. The examiner can normally be reached on Tuesday to Friday from 6:40 AM to 4:10 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden, can be reached on (703) 308-2920.

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When filing a response by fax the following numbers should be used as indicated:

Official After Final Response Fax: (703) 305-3599

All Other Official Response Faxes: (703) 305-7718

Unofficial Faxes (proposed claims, draft copies of responses, etc.): (703) 305-7719

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


William H. Beisner
Primary Examiner
Technology Center 1700
6/18/96